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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/963,239 | 11/03/1997 | EDWARD J. GOUGH | 13724-787 | 9828 |

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| EXAMINER | |
|---|---|
| PEFFLEY, MICHAEL F | |
| ART UNIT | PAPER NUMBER |
| 3739 | |

DATE MAILED: 11/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 08/963,239 | Applicant(s) GOUGH ET AL. | |
|---|---|---|---|
| | Examiner Michael Peffley | Art Unit 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *53-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *13 February 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's amendments and comments, received February 13, 2002, have been fully considered by the examiner. This application had previously been suspended pending the outcome of Interference No. 104,290. A decision has been reached in Interference No. 104,290 and the examiner is now resuming action on the instant application.

***Priority***

There have been various assertions to priority to different applications, most notably to US Application No. 08/290,031, now US Patent No. 5,536,267. The priority to the '267 patent was established via incorporation by reference, which incorporation by reference has raised inventorship issues since none of the inventors of the instant application are named in the '267 patent. The examiner reminds applicant that it is improper to incorporate-by-reference essential material from a US Patent or application which itself incorporates-by-reference essential subject matter from another US Patent or application (see MPEP 608.01(p)). Applicant has now withdrawn any claim of priority to the '267 patent. Currently, the instant application claims priority as being a continuation-in-part of US Patent Application No. 08/605,323, filed February 14, 1996, which is a continuation-in-part of US Patent Application No. 08/515,379, filed August 15, 1995. As such, the instant is deemed to have an earliest filing date of August 15, 1995.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al ('743).

Edwards et al disclose a method of ablating tumorous tissue comprising providing an apparatus having an elongated delivery device (22) with a tissue piercing distal end (14 – see Figure 3), at least one RF electrode (12) having a tissue penetrating distal tip and having deployed and non-deployed states. As seen in Figure 3, the electrode exhibits a curvedly changing direction of travel as it is advanced from the elongated delivery device. In use, the device is deployed into tissue, and energy is delivered to the RF electrode to ablate the tissue. The electrode may further include a temperature sensor (col. 5, line 65 to col. 6, line 6), and there is a control system (38) which cuts off power when a certain temperature condition is met. See col. 7, lines 25+ and particularly col. 8, lines 38-47.

Claims 57-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al ('267).

Edwards et al disclose a method of ablating tumor tissue comprising providing an ablation apparatus having a plurality RF antennas (20), positioning the antennas (20) adjacent target tissue to define an ablation volume (see Figures 14 and 15), delivering energy to ablate the tissue, and monitoring the temperature of the tissue and ceasing delivery of energy upon reaching a predetermined temperature (see col. 11, lines 3-26). Edwards et al also disclose the provision of fluids, including chemotherapeutic and conductive solutions, to tissue during treatment (col. 9, lines 1-10). The deployed electrodes may be deployed with curvature in a lateral direction (see Figures 7 and 13), and any reasonable surface size may be achieved through the use of movable insulators located on each of the antennas.

Claims 57-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al ('675).

Edwards et al disclose a method for treating tumors which includes the steps of providing an ablation apparatus having a plurality of antennas (36), positioning the antennas adjacent to target tissue (Figure 1) and delivering energy to the antennas to ablate targeted tissue. See also col. 5, lines 9-27. Edwards et al also disclose various sensors, including temperature sensors, which are used to control the delivery of RF energy (see Abstract, col. 5, lines 40-43 and col. 13, lines 5-18). Edwards et al also disclose the delivery of various fluids to tissue during treatment (col. 7, lines 44+) and

the antennas may be deployed laterally from the elongate member with curvature (see Figures 8 and 9). The antennas are provided with an insulation which may be advanced/retracted in order to control the size of the energy delivery surface (col. 5, lines 20-25).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al ('441) or Edwards et al ('597) in view of the teaching of Edwards et al ('675).

Edwards et al ('441) and Edwards et al ('597) disclose an apparatus including an elongated delivery device (42) having a tissue penetrating distal end (40) and at least one electrode (38) deployable from the elongated member. The electrode is deployed with curvature (Figure 5), and the electrode is advanced into tumor tissue and energy is delivered to ablate the tumor. While Edwards et al disclose temperature sensors, there is no specific disclosure of controlling the delivery of energy, and particularly ceasing the delivery of energy, based on sensed tissue temperature.

Edwards et al ('675) as addressed in the 35 USC 102(b) rejection, discloses an analogous device, and further teaches that the temperature sensors may be used to control the output of energy delivered to the electrodes (col. 13, lines 5-18).

To have provided either the Edwards et al ('441) or the Edwards et al ('597) system with a controller to control/stop energy delivery based upon sensed temperature conditions would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards et al ('675).

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Edwards et al ('675) or Edwards et al ('267) in view of the teaching of LeVeen et al ('276).

Edwards et al ('675) and Edwards et al ('267) have been addressed previously. Neither of these references specifically disclose an elongated delivery member which includes a tissue penetrating tip as set forth in independent claim 53.

LeVeen et al disclose an analogous system whereby an elongated member is used to provide a plurality of electrodes to tumor tissue. The elongated member may include a sharpened distal tip to facilitate insertion into tissue (col. 10, lines 11+). It is noted that the instant application claims priority to August 15, 1995, and the LeVeen et al reference qualifies as prior art with an effective filing date of March 24, 1995.

To have provided either the Edwards et al ('675) or Edwards et al ('267) device with a tissue-penetrating tip on the elongated delivery member to facilitate its introduction into tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of LeVeen et al ('276).

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 5,728,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specific steps of controlling energy delivery based on sensed temperature is deemed an obvious step in view of the Gough et al disclosure. In particular, it is noted that claims 32-38 of the '143 patent are directed to a method of using the device to ablate tissue.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 19, 2002